

Glycated Haemoglobin (HbA1c) Testing Market, 2014 - 2024

2014

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3.3. HbA1c: TEST DEFINITION

Haemoglobin is an iron containing red blood cell protein that transports oxygen in the blood stream. It is of three types: HbA (97%), HbA2 (2.5%) and HbF (0.5%). HbA further comprise HbA0 and HbA1, which in turn is made up of HbA1a1, HbA1a2, HbA1b and HbA1c. If a person is suffering from diabetes, the blood glucose level increases proportionately. Glucose gets assimilated in the blood and combines with the RBC metalloprotein, i.e. haemoglobin. This results in the formation of glycated haemoglobin.

The extent of glycation of haemoglobin is directly proportional to the amount of glucose in the blood. HbA1c is formed when glucose reacts with the N-terminal valine amino acid of the beta chain of haemoglobin. The extent of glycation, which is a non-enzymatic process, is generally 60-80%.

The average life span of red blood cell is 120 days in the blood stream. Therefore, HbA1c readings are the average glucose levels for this time period. It is generally recommended by the physicians to go for HbA1c tests once every three months. The HbA1c content in newly formed cells is negligible and those that are about to die contain the maximum levels. There are certain factors which may influence results of the test. This could result in some inaccuracies and the final reading may not correlate with the actual blood glucose concentrations. Table 3.2 lists the factors which influence HbA1c reading.

Table 3.2 HbA1c Final Results: Influencing Factors

Factor	Parameter	HbA1c Result
Erythropoiesis	Iron deficiency	↑
	Vitamin B-12 deficiency	↑
	Renal impairment	↑
	Erythropoietin	↓
	Reticulocytosis	↓
	Chronic liver disease	↓
Erythrocyte destruction	Splenectomy	↑
	Haemoglobinopathies	↓
	Splenomegaly	↓
	Rheumatoid arthritis	↓
	Other medications (e.g. Anti-retrovirals, dapsone)	↓
Glycosylation rate	Vitamin C or E deficiency	↑

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↑ implies that HbA1c results may increase; ↓ implies that HbA1c results may decrease; ↕ implies that HbA1c results may increase or decrease

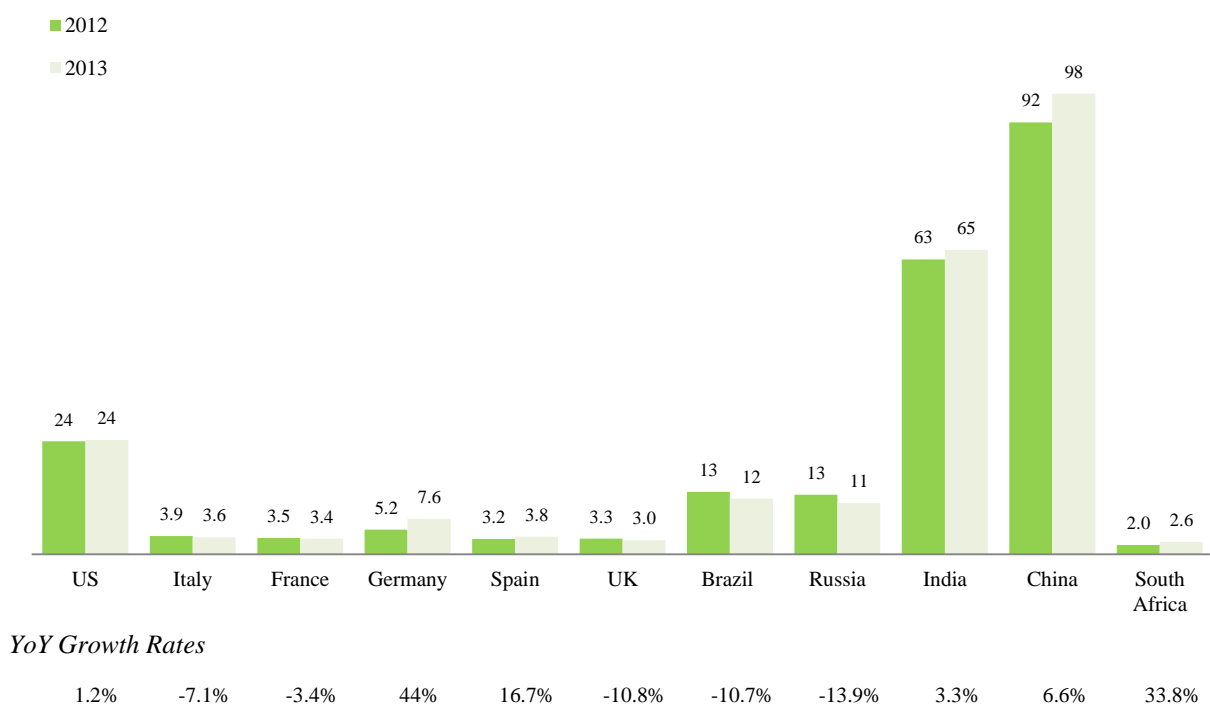
4.5. HbA1c: MAPPING THE OPPORTUNITY SIZE

The total diabetic population in 2013 was 382 million. The International Diabetes Federation expects this number to increase to 592 million by 2035, growing approximately at an annualized rate of 2%. The total global expenditure on diabetes in 2013 was reported to be USD 548 billion; this is expected to increase to USD 627 billion by 2035.¹

We have covered United States, EU5 and BRICS nations for our analysis. Figure 4.5 highlights the total number of people who were suffering from diabetes in these countries in 2012 and 2013.

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Figure 4.5 Number of People Suffering From Diabetes in EU5, US, BRICS (Million)



Source: IDF Diabetes Atlas 2012, 2013, Roots Analysis

During 2012-2013, the highest growth rate was seen in Germany though China witnessed the maximum rise of diabetic population in absolute numbers.

4.6. DIABETES AND HbA1c: REGIONAL ANALYSIS

The ADA has suggested HbA1c values ranging between 5.7-6.4% as a high risk zone. It further recommends that people having HbA1c values between this high risk zones, should get their HbA1c measured on a regular basis. Recommended HbA1c range may vary for each country according to

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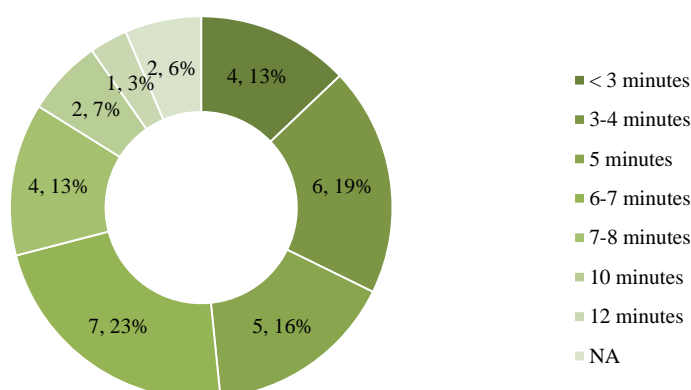
¹Source: http://www.idf.org/sites/default/files/EN_6E_Atlas_Full_0.pdf

5.5. DISTRIBUTION OF ANALYZERS BY TIME TAKEN FOR ANALYSIS

Lesser the time taken for analysis, more it is convenient for the patient to operate. Figure 5.5 highlights the distribution of POC devices by the time taken for HbA1c assay. It can be observed from the figure that the end-user has lot of options to chose from irrespective of the time taken for analysis. The maximum time taken for analysis amongst the POC devices is 12 minutes. The minimum taken taken for analysis is 7 seconds by QDxA1c.

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Figure 5.5 POC Analyzers: Distribution by Time Taken for Analysis



Source: Roots Analysis

5.6. POC MARKET ANALYSIS

This section includes the analysis of point of care devices on the basis of certain important competitive parametes which differentiate one product from another. These cover both technical and user friendly parameters. Technical parameters include time taken for analysis, amount of blood sample required, memory and precision of the analyzer. User friendly parameters include ease of sample loading, quality of the brochure provided by the company and number of user dependent steps. The details of each of these parameters are given below:

- **Time of analysis:** Time of analysis refers to the time taken by the analyzer to give the HbA1c readings on monitor. Analyzers having comparatively lesser time of analysis are preferred over the ones taking longer time for analysis.
- **Sample Amount:** It is the amount of blood sample required for testing. The sample (amount) is expressed in μL . It can either be taken from veins or capillaries. Sample taken can be either haemolysated or whole blood, depending on the analyzer in consideration.
- **Precision (%):** Coefficient of Variation (CV), is a measure of reproducibility of the results in multiple repeated measurements. Lesser the CV value, greater is the accuracy. Poor CV values

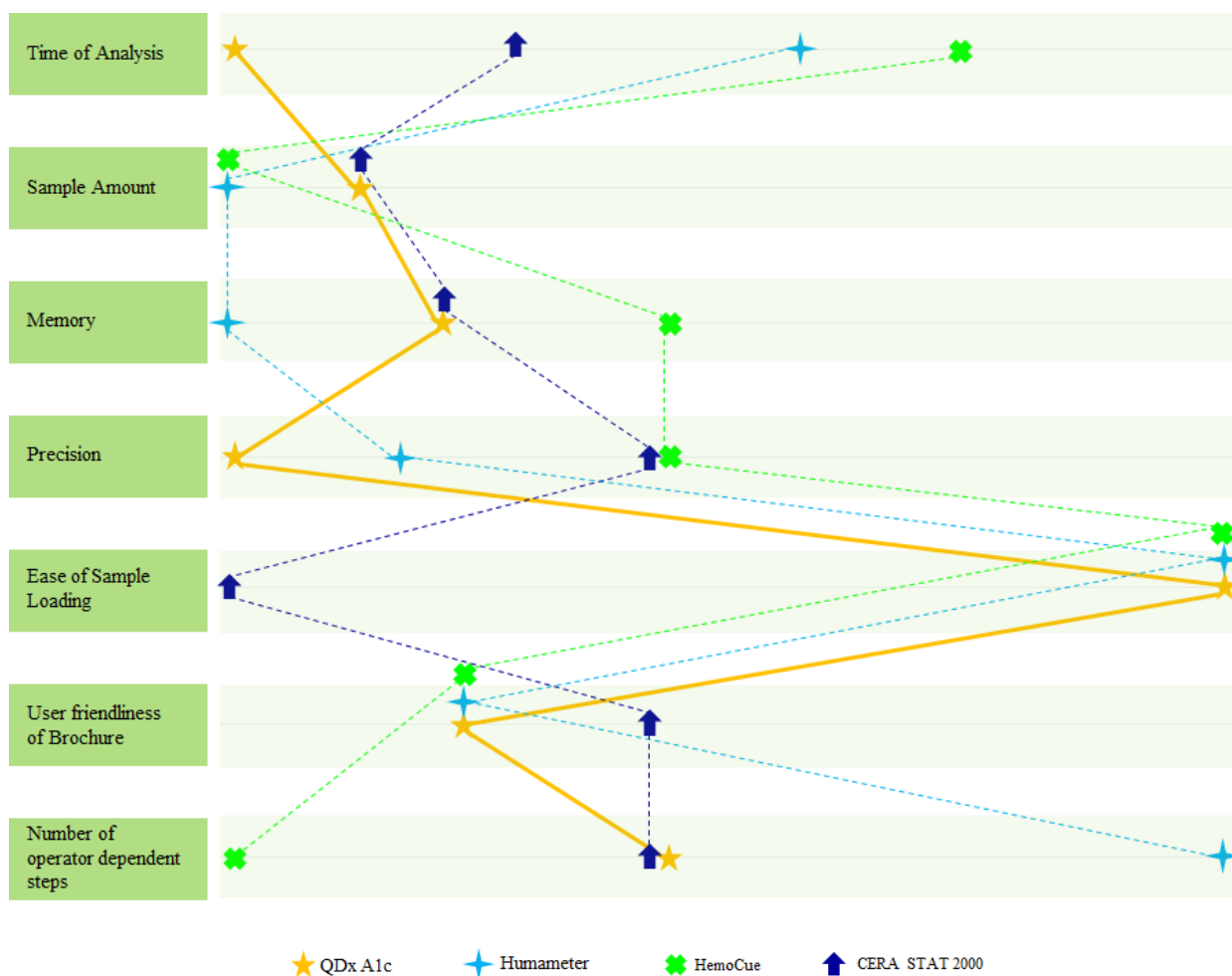
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5.7.1. CATEGORY 1 POC DEVICES

Out of 12 devices which belonged to this category, we did a detailed review of eight devices; these devices were shortlisted primarily based on the level of information available. Table 5.6 provides the details of various parameters for each of these devices.

For an easy comparison, we plotted the above parameters for all the devices (Figure 5.6 and Figure 5.7). The vertical axis lists all the parameters, each of these have been ranked for various products.

Figure 5.6 POC Market Analysis: Category 1 Devices, Set 1 Report Page 62



Source: Roots Analysis

Based on this analysis, we observe that QDx-A1c does well on many parameters vis-à-vis other products and offers best performance in terms of time of analysis and precision. CERA STAT 2000 and Humameter are the next best products. It is important to mention that the relative rankings reflect the grading on certain parameters we have discussed in this section and, as such, shouldn't be interpreted as firm recommendations for end-use.

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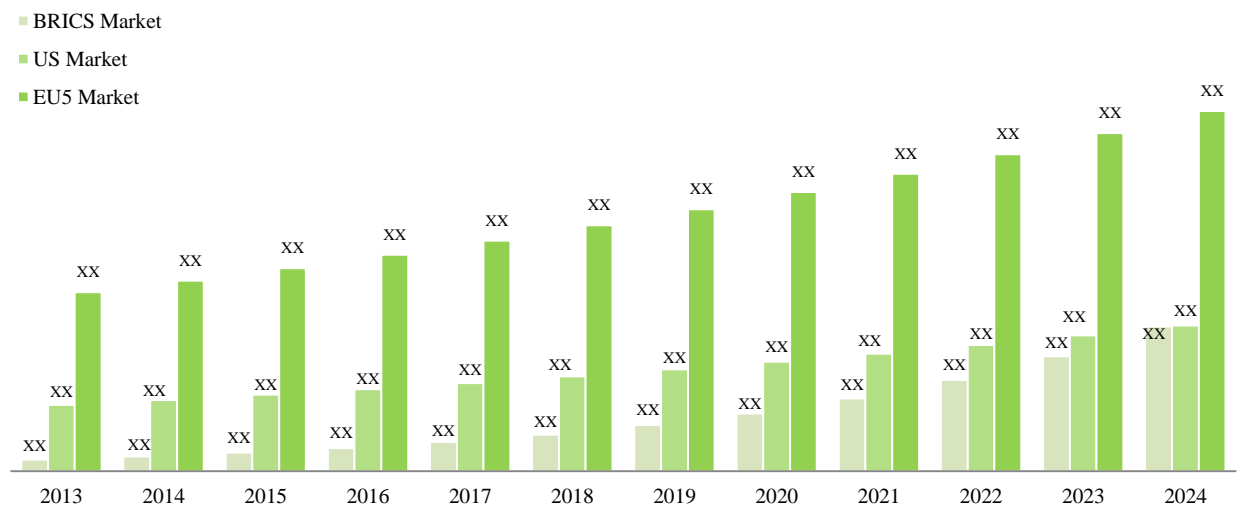
7.3. HbA1c DIABETES TESTING MARKET: GLOBAL AND REGIONAL ANALYSIS, 2014 – 2024

The total HbA1c diabetes testing market was worth USD XX billion in 2013. In our ‘base scenario’ we believe the market will grow to USD XX billion in 2024. The represents an annualized growth rate of ZZ%. In the ‘optimistic scenario’, the total market is expected to be worth USD XX billion whereas in ‘conservative scenario’ the total market is expected to be worth USD XX billion. The details of these models are provided in the appendix.

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Figure 7.2 highlights our base scenario for the likely growth in the revenues from the total number of tests conducted in the US, EU5 and BRICS countries. As is evident from the figure, we are very optimistic on the expected growth rates from the BRICS market. The primary reason for this is the low current penetration rates. India and China are the top two countries with highest number of people suffering from diabetes in 2013. With an increasing awareness of diabetes and effective treatments options, the adoption rates for HbA1c tests are likely to increase for these developing economies.

Figure 7.2 HbA1c Regional Diabetes Monitoring Market Forecast, 2014 - 2024: Base Scenario (USD Billion)



Source: Roots Analysis

The revenues from HbA1c tests were highest in EU5 in 2013. The EU5 market is expected to grow at an annualized rate of XX% and reach USD XX billion in 2024. The US HbA1c market is expected to increase from USD XX million in 2013 to USD XX million in 2024 at an annualized

Continued on Pages 129 - 133. The details of conservative and optimistic scenarios are presented in Appendices.

ORDER FORM

REPORT TITLE

Glycated Haemoglobin (HbA1c) Testing Market, 2014 - 2024

CUSTOMER DETAILS

Name	Email
Job Title	Company
Address	
City	Country
ZIP Code	Phone
VAT Number	

LICENSE TYPE (TICK ONE)

		<i>USD (\$)</i>	<i>EUR (€)</i>	<i>GBP (£)</i>
<input type="checkbox"/>	Single-user License	\$1,899	€1,482	£1,254
<input type="checkbox"/>	Site License	\$3,999	€3,120	£2,640
<input type="checkbox"/>	Enterprise License	\$6,499	€5,070	£4,290

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Select preferred currency option

- ☐ USD (\$)
☐ EUR (€)
☐ GBP (£)

Select mode of payment

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☐ I have enclosed a check, accompanied by this form, payable to Roots Analysis Private Limited

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